



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1673]

Updating Abbreviated New Drug Application Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn." This draft guidance describes a process for updating labeling for abbreviated new drug applications (ANDAs) in cases where FDA has withdrawn approval of the new drug application (NDA) for the ANDA's reference listed drug (RLD) for reasons other than safety or effectiveness. The process described in this guidance is intended to complement existing Agency authorities and processes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1673 for "Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3381, [emily.helmswilliams@fda.hhs.gov](mailto:emily.helmswilliams@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn." This draft guidance describes a process for updating labeling for ANDAs in cases where FDA has withdrawn approval of the NDA for the ANDA's RLD for reasons other than safety or effectiveness.

A generic drug is required to have the same labeling as the RLD at the time of approval, except for changes required because of differences approved under a suitability petition (see section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and 21 CFR 314.93) or because the generic drug and the RLD are “produced or distributed by different manufacturers” (see section 505(j)(2)(A)(v) of the FD&C Act and § 314.94(a)(8)(iv) (21 CFR 314.94(a)(8)(iv))). As a general matter, all holders of marketing applications for drug products have an ongoing obligation to ensure their product labeling is accurate, and not false or misleading. ANDA holders are expected to update their labeling after FDA has approved relevant changes to the labeling for the corresponding NDA RLD.

Where approval of an NDA RLD has been withdrawn, the NDA holder can no longer update labeling for the withdrawn RLD. The labeling of ANDAs that rely on the withdrawn RLD might eventually become inaccurate and outdated, resulting in labeling that is false and/or misleading, for example. Likewise, new original ANDAs that rely on the withdrawn RLD might include proposed labeling based on the last approved RLD labeling that includes outdated information that is false and/or misleading. This draft guidance clarifies that consistent with the statute, where the RLD is withdrawn, certain labeling changes may continue to be made for pending ANDAs and marketed ANDAs. This draft guidance sets forth a process for making such changes. The process described in this guidance is intended to complement existing Agency authorities and processes.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the process for updating ANDA labeling after approval of the NDA for the RLD has been withdrawn. It does not establish any rights for any person and is not binding on

FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 314.94(a)(8) and 21 CFR 314.97 have been approved under OMB Control No. 0910-0001.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-16157 Filed: 7/8/2016 8:45 am; Publication Date: 7/11/2016]